

Application No.: 10/657,550
Amendment Dated January 6, 2011
Reply to Office Action of August 6, 2010

Amendments to the Drawings:

Applicant encloses four sheets of new drawings to be submitted in this patent application.
A description of the figures has been added to the specification.

REMARKS/ARGUMENTS

The specification has been amended to explicitly incorporate the Examples section from parent application 10/414,682. As set forth in previous responses, the present application is a continuation-in-part from Ser. No. 10/414,682. The present application incorporated the subject matter of Ser. No. 10/414,682 in the "Related Applications" section of the specification. The specification was also amended to include a "Brief Description of the Figures" section to accompany the addition of the four (4) figures set forth in parent application Ser. No. 10/414,682. Applicant has not amended any of the claims.

I. Rejection under 35 U.S.C. §112

Claim 12 stands rejected under 35 U.S.C. §112, first paragraph, for containing new matter. Applicant traverses this rejection.

The Office argues that the specification does not provide support for "0.05% by weight of suspended solid fluticasone particles". The Office, however, mentions at the bottom of page 12 that Table 3 of the parent application incorporated by reference into the present application teaches a formulation having 0.05% by weight of fluticasone. The present specification has been amended to explicitly incorporate the Examples section of the parent case relating to the fluticasone study (i.e., U.S. Serial No. 10/414,682). Applicant submits that this rejection has been overcome and request withdrawal thereof.

II. Rejections under 35 U.S.C. §103

Claims 1, 4-6, 10-13, 22-25, 27-30, 35, and 77 under 35 U.S.C. §103(a) as being obvious over FLONASE from the online Physician's Desk Reference, as evidenced by the 1999-2000 Drug Information Handbook (Lacy, C.; Armstrong, L. L.; Lipsy, R. J.; Lance, L.L., Lexi-Comp, Inc.: Cleveland, pp 445-446) in view of U.S. Patent No. 6,464,958 to Bernini et al. (hereinafter "Bernini"), WO 99/18971 to Harris (hereinafter "Harris"), and U.S. Publication No. 2002/0061281 to Osbakken et al. (hereinafter "Osbakken"). Claims 71-74 stand rejected under 35 U.S.C. §103(a) as being obvious over FLONASE in view of Bernini, Harris, Osbakken, and

further in view of U.S. Patent No. 6,368,616 to Doi and U.S. Patent No. 6,608,054 to Meade. Applicant traverses all prior art rejections.

As set forth in the previously filed response, Applicant reiterates that any combination of the currently cited art does not teach, suggest, or render predictable any of the following: (1) the specifically recited particle size distribution characterized by 5 distinct levels which demonstrate surprising results; (2) an aqueous suspension of 0.04% to 0.06% by weight fluticasone having the specifically recited particle size distribution the demonstrates surprising results in combination with an antifungal agent as recited in independent claims 1, 35, and 75; (3) a nasal formulation that is sterile and has a relatively long period of stability such that after storage for 12 months at a temperature between 15 to 30°C, greater than 90% of the fluticasone originally present in the formulation still remains in the formulation as recited in claims 25 and 77. For at least these reasons, Applicant submits that each of the obviousness rejections has been overcome and requests the withdrawal of all obviousness rejections.

Additionally, Applicant submits that the fact that the claimed fluticasone distribution affords unexpected results, as discussed in the previous response, provides further evidence of the non-obviousness of the currently claimed invention. The unexpected results realized by the currently claimed invention were discussed in detail in a previous response. For at least this reason, Applicant submits that each of the obviousness rejections has been overcome and requests the withdrawal of all obviousness rejections.

III. Conclusion

In view of at least the remarks made above, Applicant submits that the pending claims are in condition for allowance. Applicant respectfully requests that the claims be allowed to issue. If the Examiner wishes to discuss the application or the comments herein, the Examiner is urged to contact the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

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therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'John E. Johnson, III', with a stylized flourish at the end.

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